MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-101078-PIP01-23-M01

Scope of the Application

Active Substance(s)

OLAPARIB

Condition(s)

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic, and lymphoid tissue).

Pharmaceutical Form(s)

Film-coated tablet; Capsule, hard; Age-appropriate oral solid dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 05/07/2023 10:25 BST an application for a Modification

The procedure started on 13/12/2023 11:28 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101078-PIP01-23-M01

Of 05/01/2024 15:53 GMT

On the adopted decision for OLAPARIB (MHRA-101078-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for OLAPARIB, Film-coated tablet; Capsule, hard; Age-appropriate oral solid dosage form , ORAL USE .

This decision is addressed to AstraZeneca UK Limited, 1 Francis Crick Avenue , Cambridge, UNITED KINGDOM, CB2 0AA

ANNEX I

1. Waiver

1.1 Condition:

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic, and lymphoid tissue). The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age. Pharmaceutical form(s): Film-coated tablet, Capsule, hard, Age-appropriate oral solid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic, and lymphoid tissue).

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients from 6 months to ≤18 years old with homologous recombination repair (HRR) mutated solid tumours.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 months to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Film-coated tablet Capsule, hard Age-appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral solid dosage form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 2 Open-label, multicentre study to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and preliminary efficacy of olaparib monotherapy in paediatric patients with relapsed or refractory solid tumours (non-CNS and primary CNS tumours) with a homologous recombination repair (HRR) deficiency for whom there are no standard treatment options. Study 3 Open-label, multicentre study to evaluate the safety, tolerability and efficacy of olaparib monotherapy in paediatric patients with relapsed or refractory non-CNS solid tumours for whom there are no standard treatment options and have Homologous recombination repair (HRR) mutations demonstrated by tumour tissue or ctDNA testing. Study 4 Randomised, controlled study to evaluate the safety, tolerability and efficacy of olaparib

		monotherapy in paediatric patients with relapsed or refractory non-CNS solid tumours for whom there are no standard treatment options who have Homologous recombination repair (HRR) mutations demonstrated by tumour tissue or ctDNA testing.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/12/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes